



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to OptiEFAX™ and maintenance of normal blood LDL-cholesterol concentrations pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Nutrilinks Sarl, submitted for authorisation of a claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations. The food that is the subject of the health claim, *Opti_{EFAX}*TM, which is standardised pure krill oil, is sufficiently characterised in relation to the claimed effect. The claimed effect, maintenance of normal blood LDL-cholesterol concentrations, is a beneficial physiological effect. The target population proposed by the applicant is the general population. No human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim. A cause and effect relationship has not been established between the consumption of *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations.

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KEY WORDS

*Opti_{EFAX}*TM, krill oil, LDL, cholesterol, health claims.

¹ On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00339, adopted on 27 June 2012.

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SUMMARY

Following an application from Nutrilinks Sarl, submitted for authorisation of a claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food that is the subject of the health claim is *Opti_{EFAX}*TM, which is standardised pure krill oil. The Panel considers that the food, *Opti_{EFAX}*TM, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

The claimed effect is maintenance of normal blood LDL-cholesterol concentrations. The target population proposed by the applicant is the general population. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

One human intervention study was provided as pertinent to the claim. This was a 90-day, double-blind, randomised, parallel study in which 120 subjects, some of whom were on lipid lowering medication throughout the study, were randomly assigned to consume daily either 2 or 3 g krill oil, 1 or 1.5 g krill oil, 3 g of fish oil, or placebo. The Panel notes that the nature of the placebo was not reported, that no information about the baseline characteristics of groups with respect to medication use was provided, that medication use and repeated measures were not taken into account in the analysis and that the presentation of data and of the results from statistical analyses does not allow an interpretation of the results. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction in disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Art 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 15/02/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 19/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 24/04/2012.
- The scientific evaluation procedure started on 27/04/2012.
- During its meeting on 27/06/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to *Opti*_{EFAX}TM and maintenance of normal blood LDL-cholesterol concentrations.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to *Opti*_{EFAX}TM and maintenance of normal blood LDL-cholesterol concentrations.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of *Opti*_{EFAX}TM, a positive assessment of its safety, nor a decision on whether *Opti*_{EFAX}TM is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Nutrilinks Sarl, Chemin de Beau-rivage 7, P.O. Box 96, CH-1000 Lausanne 21, Switzerland.

Food/constituent as stated by the applicant

According to the applicant, the food, which is the subject of the claim, is *Opti_{EFAX}*TM, a standardised pure krill oil extract.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to maintaining healthy blood levels of LDL cholesterol.

Wording of the health claim as proposed by the applicant

The following wordings are proposed by the applicant: "*Opti_{EFAX}*TM helps to maintain healthy blood levels of LDL cholesterol".

Specific conditions of use as proposed by the applicant

The applicant proposes the target population to be the general population and conditions of use of one capsule of a food supplement with 1 to 1.5 g of the standardised pure krill oil containing defined minimal amount of omega-3 fatty acids, specifically EPA and DHA, provided in soft or a hard capsule with water, preferably in the morning, during 90 consecutive days.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is *Opti_{EFAX}*TM, which is standardised pure krill oil.

Krill oil is oil, which is extracted from the crustacean *Euphausia superba* (Antarctic Krill). It has been authorised as novel food ingredient⁵. The krill oil, which is the subject of the claim, complies with Commission Decision 2009/752/EC. The main fatty acids contained in the krill oil, which is the subject of the claim, are eicosapentaenoic acid (EPA, C20:5, 22 %), palmitic acid (C16:0, 20 %), docosahexaenoic acid (DHA, C22:6, 13 %), oleic acid (C18:1 n-9, 10 %), myristic acid (C14:0, 9 %), and vaccenic acid (C18:1 n-7, 7 %). The content of esterified astaxanthin amounts to around 1,000 to 1,500 mg/kg. Fatty acids and astaxanthin can be measured in foods by established methods. Information on the stability and the batch-to-batch variability of the product has been provided.

The Panel considers that the food, *Opti_{EFAX}*TM, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

⁵ 2009/752/EC: Commission Decision of 12 October 2009 authorising the placing on the market of a lipid extract from Antarctic Krill *Euphausia superba* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2009) 7647), OJ L 268, 13.10.2009, p. 33–34.

2. Relevance of the claimed effect to human health

The claimed effect is maintenance of normal LDL-cholesterol concentrations. The target population proposed by the applicant is the general population.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.1 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Pubmed, ScienceDirect, Blackwell Synergy, Wiley InterScience, Mary Ann Liebert, Scirus, IBIDS, SciFinder Scholar, Pascal, Google and SCOPUS with the search terms [“Neptune krill oil”] AND [“cholesterol”] for publications between January 2000 to May 2011. Hand searches in specialised libraries and web research were also performed. Upon request from EFSA during the validation period of the application, the applicant extended the literature search to cover also krill oils other than those manufactured according to the applicant’s specifications.

This literature search resulted in the identification of three human intervention studies (Bunea et al., 2004; Maki et al., 2009; Ulven et al., 2011), two of which (Maki et al., 2009; Ulven et al., 2011) were not considered pertinent to the claim by the applicant owing to compositional differences in EPA and DHA content of the krill oils administered in these studies, the absence of information about the amount of astaxanthin in the interventions and the study design.

The study by Bunea et al. (2004) was a 90-day, double-blind, randomised, parallel study in which 120 subjects (m/f ratio not reported) with elevated blood cholesterol and triglyceride concentrations were randomly assigned to consume daily either 2 or 3 g krill oil (group A: n=30, 2 g: n=19, 3 g: n=11, dose based on BMI), 1 or 1.5 g krill oil (group B: n=30, 1 g: n=23, 1.5 g: n=7, dose based on BMI), 3 g of fish oil (group C: n=not reported) or placebo (group D: n=not reported, nature of placebo not reported). The krill oil administered in the study was manufactured in line with the applicant’s specifications. Subjects were allowed to continue lipid lowering medication throughout the study (n per group not reported). It was estimated that a sample size of 30 subjects per group was needed to detect a 15 % change from baseline in total cholesterol with 90 % power. Blood lipids were measured at baseline and at 30 and 90 days of the study. No information about drop-outs has been provided in the publication. Data were analysed using one-way analysis of variance. Results have been given without indication of dispersion measures and between-group comparisons have been reported without any indication of the significance level obtained. The Panel notes that the nature of the placebo was not reported, that no information about the baseline characteristics of groups with respect to medication use was provided, that medication use and repeated measures were not taken into account in the analysis and that the presentation of data and of the results from statistical analyses does not allow an interpretation of the results. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Opti*_{EFAX}TM and maintenance of normal blood LDL-cholesterol concentrations.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, *Opti_{EFAX}*TM, which is standardised pure krill oil and subject of the claim, is sufficiently characterised in relation to the claimed effect.
- Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of *Opti_{EFAX}*TM and maintenance of normal blood LDL-cholesterol concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on *Opti_{EFAX}*TM and maintenance of normal LDL-cholesterol concentrations pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0334_BE). April 2012. Submitted by Nutrilinks Sarl.

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- Ulven SM, Kirkhus B, Lamglait A, Basu S, Elind E, Haider T, Berge K, Vik H and Pedersen JI, 2011. Metabolic effects of krill oil are essentially similar to those of fish oil but at lower dose of EPA and DHA, in healthy volunteers. *Lipids*, 46, 37-46.

GLOSSARY AND ABBREVIATIONS

BMI Body mass index

DHA Docosahexaenoic acid

EPA Eicosapentaenoic acid

LDL Low-density lipoproteins